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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Registration Review.

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Introduction

The Pesticide Re-evaluation Division (PRD) requested that the Health Effects Division (HED) conduct an exposure and risk assessment for the registered uses of aldicarb as part of registration review. This memorandum contains HED's occupational/residential exposure and risk

assessment required during registration review to reflect the updated science policies and procedures.

It is HED policy to use the best available data to assess exposure. Several sources of generic data were used in this assessment as surrogate data in the absence of chemical-specific data, including Pesticide Handlers Exposure Database Version 1.1 (PHED 1.1); the Agricultural Handler Exposure Task Force (AHETF) database; other registrant-submitted exposure monitoring studies (MRID 43852501). Some of these data are proprietary, and subject to the data protection provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Note: This memorandum was reviewed by the Exposure Science Advisory Committee (ExpoSAC) on 06/04/15.

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1.0 Executive Summary

The Health Effects Division (HED) has conducted an exposure and risk assessment for the registered uses of aldicarb as part of registration review. This memorandum contains HED's occupational/residential exposure and risk assessment required during registration review to reflect the updated science policies and procedures.

Aldicarb [2-methyl-2-(methylthio)propanal O-[(methylamino)carbonyl]oxime] is a carbamate insecticide that is marketed only as a granular product (with either low-dust corn cob grit or vinyl-coated gypsum-based substrates) with a concentration of 15 percent active ingredient. Aldicarb is used to control soil borne pests including mites, various insects, and nematodes on dry beans, sugar beets, cotton, peanut, sweet potato, and soybean.

The label-required Personal Protective Equipment (PPE) varies depending on the handling scenario & packaging of the formulation (i.e., substrate of the granular formulation). For open pour handling, the PPE is coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material, and chemical-resistant footwear plus socks. In addition, during loading, equipment cleaning or repair, or spill clean-up, the labeling requires handlers to wear protective eyewear (goggles or face shield), a chemical-resistant apron, and a NIOSH-approved respirator with a dust/mist filter. The exception to the above PPE requirements are when engineering controls (i.e., a closed loading/application system) are used. The restricted entry interval (REI) on the current labeling is 48 hours.

In acute lethality studies, aldicarb is highly toxic *via* the oral, dermal, and inhalation routes of exposure (Toxicity Category 1). It is not a dermal sensitizer, but due to severe effects (death) following corneal and dermal dosing, dermal and eye irritation studies were waived. Aldicarb toxicity studies have demonstrated cholinesterase inhibition (ChEI) activity in whole blood, plasma, red blood cells (RBC) and brain of rats, mice, and dogs following acute, subchronic, and chronic exposures and in plasma and RBC in humans following acute exposure. The toxicological endpoints selected for the dermal and inhalation routes of exposure were based on a common toxic effect (RBC ChEI) from an intentional dosing human oral study¹; therefore, these routes were combined for the occupational exposure and risk assessment. For the occupational risk assessment, the level of concern (LOC) is for Margins of Exposure (MOEs) less than 10.

There are no currently registered residential uses. The potential for spray drift exposure is considered negligible because of the aldicarb product formulation (granular) and immediate soil incorporation of the product.

There is potential for occupational handler exposure. The occupational assessments were completed based on an available chemical-specific occupational exposure monitoring study² (used to assess the use of PPE during open pour/open cab applications) and based on surrogate data [i.e., the Pesticide Handlers Exposure Database (PHED)]; used to assess the use of

¹ Ethics Review Available: at [HYPERLINK "<http://www.epa.gov/osa/hsrb/files/april2006mtgfinalreport62606.pdf>"]

² Worker Loader and Applicator Exposure to Temik 15G (10/12/95) Sponsor: Rhone Poulenc Ag Company, 2 TW Alexander Drive, Research Triangle Park NC 27709 (EPA MRID 438525-01)

engineering controls during applications]. Occupational handlers are assessed assuming short- and intermediate-term dermal and inhalation exposure. There is no quantitative post-application assessment based on the limited exposure potential since aldicarb is soil incorporated.

For the open pour/open cab application scenarios, using chemical-specific unit exposure data and assuming use of label required PPE (i.e., a double layer of clothing and a standard filtering facepiece respirator), there are combined dermal and inhalation risk estimates of concern (i.e., MOEs are < 10) for two scenarios. Mixer/loader risk estimates are of concern for the use on sugar beets at 4.95 lb ai/A (MOE = 4.5) and 3 lb ai/A (MOE = 7.4). For the closed loading/closed cab application scenarios (i.e., engineering controls), using available surrogate unit exposure data for engineering controls, all combined dermal and inhalation risk estimates are of concern (i.e., MOEs ≤ 10).

The registered aldicarb granular product, which has either a low-dust corn cob grit or vinyl-coated gypsum-based substrate, is considered a low-dust formulation relative to the available surrogate unit exposure data from PHED (which is based on clay-based substrate granular formulations). Exposure and risk estimates for handlers using the closed loading scenarios may be considered overestimates as the PHED surrogate unit exposures are based on granular formulations which are “dustier” than the low-dust formulations such as the aldicarb products (low-dust corn cob grit and vinyl-coated gypsum based substrates).

Based on the Agency's current practices, a quantitative non-cancer occupational post-application inhalation exposure assessment was not performed for aldicarb at this time. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for aldicarb.

Human Studies Review

An intentional dosing human oral study was used for selection of points of departure in prior risk assessments. This study has been reviewed by EPA's HSRB, as required by EPA's Human Subjects Protections Rule (40 CFR part 26 (effective April 7, 2006)). The HSRB discussed the study extensively during a meeting held on April 2-4, 2006 and concluded that the cholinesterase data from the aldicarb human study were reliable for use in the aldicarb single chemical aggregate risk assessment. Additionally, it was concluded that there was no clear and convincing evidence of significant deficiencies in the ethical procedures that could have resulted in serious harm (based on the knowledge available at the time the study was conducted), nor that information provided to participants seriously impaired their informed consent. The final report of the HSRB is available at [[HYPERLINK "http://www.epa.gov/osa/hsrb/files/april2006mtgfinalreport62606.pdf"](http://www.epa.gov/osa/hsrb/files/april2006mtgfinalreport62606.pdf)] .

The PHED has been reviewed from an ethics perspective and no issues were found which would preclude its use in the risk assessment process. The chemical-specific study (MRID 43852501) was also reviewed for ethical requirements pertaining to the usability of data and

found to be acceptable for risk assessment.³ Descriptions of data sources, as well as guidance on their use, can be found at the Agency website⁴.

2.0 Risk Assessment Conclusions and Recommendations

There are occupational handler risk estimates of concern for several scenarios, depending on the application equipment/formulation combination, including both the open pour/open cab and closed loading/closed cab systems.

There is no aldicarb chemical-specific data for closed loading systems (i.e., engineering controls); therefore, HED used surrogate unit exposure values from PHED to quantitatively calculate risk estimates for closed loading systems. Risk estimates for closed loading systems are of concern (MOEs < the LOC of 10) for both loading and applicator handler scenarios. However, exposure and risk estimates for handlers using the closed loading scenarios may be considered overestimates as the PHED surrogate unit exposures are based on a clay-based substrate granular formulation which is “dustier” than low-dust formulations such as the aldicarb products (low-dust corn cob grit and vinyl-coated gypsum based substrates).

There is no quantitative risk assessment for residential exposure because there are no registered residential uses. In addition, there is no quantitative spray drift assessment based on the granular formulation type and the soil incorporation. There are no exposure data requirements for aldicarb.

2.1 Summary of Risk Estimates

The following summarizes the occupational handler risk estimates based on the available toxicity and exposure data.

Open Mixing/Loading and Open-cab Application Using Label-specified PPE:

- Mixer/loader scenarios (using chemical-specific data):
 - Sugar beets at 3 & 4.95 lbs ai/A (MOEs = 7.4 and 4.5, respectively)

Closed Mixing/Loading and Closed-cab Application (i.e., engineering controls):

- Mixer/loader scenarios (using surrogate exposure data):
 - All scenarios (total MOE ranges from 0.12 to 0.99 based on a LOC of 10)
- Applicator scenarios (using surrogate exposure data):
 - All scenarios (total MOEs ranges from <1 to 3.9 based on a LOC of 10)

3.0 Hazard Characterization

Aldicarb has an adequate toxicity database to conduct human health risk assessment.

³ HSRB Report: <http://www.epa.gov/osainter/hsrb/files/meeting-materials/apr-4-6-2006-public-meeting/april2006mtgfinalreport62606.pdf>

⁴ [HYPERLINK "<http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>"]

Acute Toxicity

In acute lethality studies, aldicarb is highly toxic *via* the oral, dermal, and inhalation routes of exposure (Toxicity Category 1). It is not a dermal sensitizer, but due to severe effects (death) following corneal and dermal dosing, dermal and eye irritation studies were waived.

Table 3.0.1 Acute Toxicity Profile – Aldicarb.				
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral - Rat	00057333	LD ₅₀ = 0.8 mg/kg/day	I
870.1200	Acute dermal - Rat	00091241 00069916	LD ₅₀ = 20 mg/kg/day, water LD ₅₀ = 5 mg/kg, propylene glycol	I
870.1300	Acute inhalation - Rat	00069916 00057333	LC ₅₀ < 0.007 mg/L	I
870.2400	Acute eye irritation - Rabbit	00069916	No corneal irritation at lethal dose	N/A
870.2500	Acute dermal irritation - Rabbit	00069916	None at fatal levels	N/A
870.2600	Skin sensitization - Guinea Pig	N/A	N/A	N/A

Toxicological Points of Departure (PODs) Used for Risk Assessment

Aldicarb toxicity studies have demonstrated inhibition of cholinesterase activity in whole blood, plasma, red blood cells (RBC) and brain of rats, mice, and dogs following acute, subchronic, and chronic exposures and in plasma and RBC in humans following acute exposure. It should be noted that aldicarb-induced ChEI has been shown to be reversible in less than 24 hours. Both the acute and subchronic rat neurotoxicity studies show a variety of typical clinical signs of ChEI after oral exposures to aldicarb, including decreased motor activity, lacrimation, tremors, salivation, pinpoint pupils, and decreased grip strength. Aldicarb did not result in developmental toxicity in either rats or rabbits or in reproductive effects in the rat multi-generation reproduction study. Additionally, there was no developmental toxicity in the developmental neurotoxicity study in rats.

In an acute oral study conducted in human volunteers, aldicarb treatment of both males and females resulted in statistically significant inhibition of both RBC and plasma cholinesterase. The results of the acute oral human study suggest a two-fold difference between animals and humans with respect to toxic responses following acute exposure to aldicarb, with human being the more sensitive species. HED selected a Benchmark Dose Level (BMDL₁₀) as a point of departure for the dermal and inhalation routes of exposure [0.013 mg/kg/day] based on RBC ChEI.

The human study was reviewed by the Human Studies Review Board (HSRB), who concluded that use of the human study endpoint was appropriate for human health risk assessment. Because

these human data are considered reliable, and the study is considered scientifically valid, at this time the Agency considers the human study to be the most suitable for the single-chemical risk assessment.

The specific toxic effect (cholinesterase inhibition) is common to the dermal, and inhalation routes; therefore, these routes can be combined for risk assessment.

For the occupational risk assessments, the level of concern (LOC) is for MOEs less than 10. The LOC is based on a 10X for intra-species, and a 1X for interspecies (reduced from 10X) because the endpoint is derived from a human study.

Aldicarb is classified as not likely to be carcinogenic to humans, based on the lack of evidence of carcinogenicity in studies in rats and mice and the absence of a mutagenicity concern. Therefore, an exposure assessment for cancer risk assessment is not required.

Table 3.0.2. Summary of Toxicological Doses and Endpoints for Aldicarb for Use in Risk Assessments.				
Exposure Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors ¹	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Exposures (Short- and Intermediate-Term)	BMDL ₁₀ = 0.013 mg/kg/day DAF = 100%	UF _H = 10 UF _A = 1x	LOC for MOE = 10X	Human oral study MRIDs 43829602, 45068601, 43442302, 43442305, 42373001 BMD ₁₀ = 0.02 mg/kg, based on RBC cholinesterase inhibition
Inhalation Exposures (Short- and Intermediate- Term)	BMDL ₁₀ = 0.013 mg/kg/day	UF _H = 10 UF _A = 1x	LOC for MOE = 10X	Human oral study MRIDs 43829602, 45068601, 43442302, 43442305, 42373001 BMD ₁₀ = 0.02 mg/kg, based on RBC cholinesterase inhibition
Cancer	Classification: Aldicarb is classified as Category E, Evidence of Non-Carcinogenicity for Humans, based on the lack of evidence of carcinogenicity in studies in rats and mice and the absence of a mutagenicity concern.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_A = extrapolation from animal to human (interspecies); to human is not warranted due to the PoD based on human RBC cholinesterase data. BMDL₁₀ = Benchmark Dose estimate based on the lower 95% confidence interval where 10% ChEI would be observed. MOE = margin of exposure. LOC = level of concern.

Absorption

Since no inhalation absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure. No acceptable dermal absorption study was submitted, therefore a default value of 100 percent dermal absorption factor was used to estimate dose. Given that aldicarb is handled only as a granular, it is unlikely that 100 percent absorption would occur; however, the exact absorption factor could not be determined from the available toxicological studies.

Body Weight

The standard body weight for the general population (80 kg) was used for all exposure scenarios for adults covered in this risk assessment since the endpoints selected were not developmental and/or fetal effects.

4.0 Use Profile

Aldicarb is a broad spectrum insecticide and is currently registered as a granular formulation that is only applied via soil incorporation (EPA Reg. #87895-1). It is registered for use on a number of agricultural crops via ground-based application equipment. Table 4.1 provides additional detail on the registered use sites.

The registered product is classified as a Restricted Use Pesticide (RUP) and may be purchased and used only by certified applicators or persons under their direct supervision. As an RUP the aldicarb product labels contain substantial protective measures to prevent worker exposure.

Aldicarb handlers must use either:

- Engineering Controls (i.e., a closed loading system), or
- a minimum of coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material, and chemical-resistant footwear plus socks. In addition, during loading, equipment cleaning or repair, or spill clean-up, handlers must wear protective eyewear (goggles or face shield), a chemical-resistant apron, and a NIOSH-approved respirator with a dust/mist filter with the MSHA/NIOSH approval number prefix TC-21C or any N, R, P or HE filter.

The available product label indicates that the product can be used generally once or twice per growing season (pre-plant or pre-plant plus early post-emergence), depending on the pest to be treated. The intended pests for the maximum application rates are generally nematodes, and the lesser rates for mites, thrips, mexican bean beetles, and other pests.

Table 4.1 provides a summary of the pests and directions per use for each target crop.

Table 4.1. Summary of Directions for Use of Aldicarb.						
Applic. Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Dry Bean						
Motorized Ground Equipment	15% ai granular 87895-1	2.1 [nematodes]	1	2.1	90	<ul style="list-style-type: none">Apply granules in seed furrow & immediately cover with soil by mechanical means.FOR USE ONLY IN: Colorado, Oregon, Washington, Idaho, & Michigan
		1.05 [aphids]	1			
		0.75 [seedcorn maggot]	1			
Sugar Beet						
Motorized Ground Equipment	15% ai granular 87895-1	4.95 [nematodes]	1 at planting application & 2 post-emergence applications	4.2 in California 4.95 in other states	90	<ul style="list-style-type: none">Apply granules in a 4 to 6 inch band and immediately cover w/ soil by mechanical means.Plant seed into or above treated zoneFOR USE ONLY IN: California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington and Wyoming.
		3 [leafminers leafhoppers]				<ul style="list-style-type: none">Drill granules 1 to 3 in. below seedline. Granules can be placed in seed furrow if rate does not exceed 1.05 lb ai/acre.
		2.1 [aphids]				
Cotton						
Motorized Ground Equipment	15% ai granular 87895-1	1.05 [nematodes]	1 (at-plant) 1 (post-emergence)	3.15	90	<ul style="list-style-type: none">Max single application rateApply granules in the seed furrow and immediately cover with soil by mechanical means.
		0.75 [aphids/thrips]			90	<ul style="list-style-type: none">Apply granules in the seed furrow and immediately cover with soil by mechanical means.
		2.1 [side dress applications]			90	<ul style="list-style-type: none">Max single rate for side dress applicationsApply granules in the seed furrow and immediately cover with soil by mechanical means.
Peanut						
Motorized Ground Equipment	15% ai granular 87895-1	1.5	(post-emergent rate; split application)	2.55	90	<ul style="list-style-type: none">Do not make more than one application per crop per year in states other than Alabama, Florida, Georgia, North Carolina, Oklahoma, Texas & Virginia.

Table 4.1. Summary of Directions for Use of Aldicarb.						
Applic. Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
		[nematodes /post-pegging]				<ul style="list-style-type: none">• Apply granules in seed furrow & immediately cover w/ soil by mechanical means.• Post-emergence applications are permitted only in fields where overhead irrigation is available.
		1.05 [nematodes/thrips]	At-planting			<ul style="list-style-type: none">• Do not make more than one application per crop per year in states other than Alabama, Florida, Georgia, North Carolina, Oklahoma, Texas & Virginia.• Apply granules in seed furrow & immediately cover w/ soil by mechanical means.
Sweet Potato						
Motorized Ground Equipment	15% ai granular 87895-1	3 [nematodes/high rate]	Pre-plant or at-plant	3	120	<ul style="list-style-type: none">• For use only in Louisiana and Mississippi.• Apply granules in a 12-in. band over open furrow or soil surface and cover immediately during bed forming by mechanically hilling up 8 to 10 inches.
		1.5 [nematodes/lower rate]				
Soybean						
Motorized Ground Equipment	15% ai granular 87895-1	1.05 [mexican bean beetle /thrips]	1 application /per crop /per year	1.05	90	<ul style="list-style-type: none">• FOR USE ONLY IN: Georgia, North Carolina, South Carolina, & Virginia• Apply granules in seed furrow and immediately cover with soil by mechanical means.
		0.75 [nematodes /thrips]		0.75		

5.0 Residential Exposure and Risk Estimates

A quantitative residential assessment was not conducted because aldicarb is an RUP and there are no currently registered non-occupational (residential) uses.

6.0 Non-Occupational Spray Drift Exposure and Risk Estimates

Off-target movement of pesticides can occur via many types of pathways and it is governed by a variety of factors. However, the aldicarb end use product is formulated as a granular and will not result in spray drift because of how it is applied (pre-plant/post-emergent soil incorporation).

7.0 Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Estimates

There is an available air monitoring study⁵ conducted in California by the California Air Resources Board (CARB). The report presents the results of application air monitoring (in Fresno County) and ambient air monitoring (in Fresno and Kern Counties).

Application site air monitoring (i.e., also known as field volatility) refers to the collection of air samples around the edges of a treated field during and after a pesticide application. Samples are generally collected for short intervals (e.g., < 8 hours), for at least the first day or two after application with subsequent samples increasing in duration. In this type of study, it is typically known when an application occurred, the equipment used for the application, and the application rate. Application site monitoring data represents an exposure to vapors at or near the field edge resulting from an application.

Ambient air monitoring typically is focused on characterizing the airborne pesticide levels within a localized airshed or community structure of some definition (e.g., city, township, or municipality). This type of monitoring effort also can be focused on capturing chronic background levels or other temporal characteristics of interest such as focusing on seasonal pesticide use patterns. Typically, samples are generally taken for 24 consecutive hours and collected at the same site over an extended period of time (e.g., several weeks or months). In contrast to application site air monitoring, information on the precise timing and location of pesticide applications are rarely collected in ambient air monitoring studies. However, this does not mean that an application did not occur near an ambient sampler during the monitoring period.

Two application studies were conducted in Fresno County; however, due to problems with the first study, which was associated with cotton planting, a second study was conducted which was associated with cotton “at first squaring.” First squaring refers to a process of manual weed control (tilling) during which the insecticide is applied to the cotton row berms. Of the twenty application samples collected during the first study, two were found to be detected (meaning results were below the limit of quantitation but equal to or above the limit of detection) and the remaining 18 were less than the limit of detection (LOD) of 0.050 ug/sample. For the second

⁵ *Report for the Application and Ambient Air Monitoring of Aldicarb*. California Environmental Protection Agency Air Resources Board. November 16, 1998. <http://www.cdpr.ca.gov/docs/emon/pubs/tac/tacpdfs/aldicarb.pdf>

application study, all four background samples had results less than the LOD. Of the twenty-four application samples collected, all were found to be less than the LOD of 0.050 ug/sample.

Ambient monitoring was initially conducted during a three week period from March 24 to April 11, 1997 in Fresno County. The monitoring was scheduled to coincide with cotton planting and the aldicarb samplers were collocated with samplers being used for an ambient phorate air monitoring study. No detectable levels of aldicarb were observed during the first three weeks of monitoring in Fresno County and so the remaining 3 weeks of monitoring was conducted in June in Kern County. Of the 60 ambient samples collected in Fresno County and the 55 collected in Kern County, all were found to be less than the LOD of 0.050 ug/sample.

8.0 Occupational Exposure and Risk Estimates

8.1 Occupational Handler Exposure/Risk Estimates

HED uses the term handlers to describe those individuals who are involved in the pesticide application process. HED believes that there are distinct job functions or tasks related to applications and exposures can vary depending on the specifics of each task. Job requirements (amount of chemical used in each application), the kinds of equipment used, the target being treated, and the level of protection used by a handler can cause exposure levels to differ in a manner specific to each application event.

Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used, occupational handler exposure is expected from the proposed uses. The quantitative exposure/risk assessment developed for occupational handlers is based on the occupational handler crop scenarios (and application rates) identified in Section 4.0.

Occupational Handler Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments. Each assumption and factor is detailed below on an individual basis.

Unit Exposures: It is the policy of HED to use the best available data to assess handler exposure. For this assessment, two main sources of data were used:

- The first source of data was a chemical-specific study (MRID 43852501⁶) that collected occupational handler dermal and inhalation exposure data representative of the registered “low dust” formulation. A summary of the study data as collected is included in Appendix B. Additional details on the study description and specifics of the data can be found in a previous assessment (Memo, J. Dawson, D311821, 1/11/15). For scenarios representing open loading and open cab application of low dust corn cob granules, unit exposure data from the chemical-specific study were used. It should be noted that the study was conducted without handlers wearing a respirator; however, the currently registered label requires handlers wear a respirator. Therefore, the inhalation unit exposures were adjusted to account for current label PPE (i.e., filtering facepiece

⁶ EPA MRID 43852501: Rosenheck, L., Schuster, L. (1995) Worker Loader and Applicator Exposure to Temik 15G. Study number 94388, Unpublished study prepared by ABC Laboratories, Pan-Ag Division; Rhone-Poulenc Ag Company.

- respirator) [i.e., an 80% assumed reduction from the inhalation unit exposure).
- The second source of data includes generic handler data. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as “unit exposures”, are outlined in the “Occupational Pesticide Handler Unit Exposure Surrogate Reference Table”, which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at the Agency website⁷. These data were used to assess scenarios representative of closed loading systems (engineering controls).

Area Treated or Amount Handled:

Based on HED ExpoSAC Policy 9.1, Table 8.1.1 identifies the amount treated or handled per day per registered use site:

Table 8.1.1 – Area Treated or Amount Handled.		
Equipment Type	Area Treated/Amount Handled	Crop/Use Site
Groundboom Equipment	80 acres for typical-acreage field crops	<ul style="list-style-type: none"> Sweet potatoes
	200 acres for high acreage field crops	<ul style="list-style-type: none"> Dry beans Sugar beets Cotton Peanuts (pre-plant/at-plant) Soybean

Exposure Duration:

HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. Exposure duration is determined by many things, including the exposed population, the use site, the pest pressure triggering the use of the pesticide, and the cultural practices surrounding that use site. For most agricultural uses, it is reasonable to believe that occupational handlers will not apply the same chemical every day for more than a one-month time frame; however, there may be a large agribusiness and/or commercial applicators who may apply a product over a period of weeks (e.g., completing multiple applications for multiple clients within a region). Therefore, this document includes an occupational exposure assessment consistent with the short- and intermediate-term exposure durations discussed above.

Personal Protective Equipment: Estimates of dermal and inhalation exposure were calculated for various levels of personal protective equipment (PPE). Results are presented for loaders and applicators based on the personal protective equipment identified on the label:

- Baseline, plus chemical-resistant gloves and coveralls with a PF5 respiratory protection device or
- Engineering controls (closed loading system or closed cab).

Occupational Handler Non-Cancer Exposure and Risk Estimate Equations

⁷ [HYPERLINK "<http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>"]

The algorithms used to estimate non-cancer exposure and dose for occupational handlers can be found in Appendix A.

Combining Exposures/Risk Estimates:

Dermal and inhalation risk estimates were combined in this assessment, since the toxicological effects for these exposure routes were similar. Dermal and inhalation risk estimates were combined using the following formula:

$$[SEQ CHAPTER \h \r I] \text{ Total MOE} = \text{Point of Departure (mg/kg/day)} \div \text{Combined dermal + inhalation dose (mg/kg/day)}$$

Summary of Occupational Handler Non-Cancer Exposure and Risk Estimates

Occupational handler risk estimates are presented using both HED's standard occupational exposure methodology and the available chemical-/scenario-specific handler data, where available.

Table 8.1.2 shows loader and applicator risk estimates assuming label-specified PPE [open loading scenarios] using the available chemical-specific handler data (occupational handlers with PPE). Table 8.1.3 shows loader and applicator risk estimates assuming engineering controls (i.e. closed loading systems) are used (based on the PHED surrogate unit exposure data).

Where risk concerns exist, the combined risk estimates are driven by dermal exposure. It should be noted that an assumption of 100% dermal absorption was used in the dermal exposure/risk calculations since an acceptable dermal absorption study was not submitted. Given that the registered product is a granular formulation, it is unlikely that 100% absorption would occur.

The following risk estimates of concern were identified (and are noted in bold in the tables):

Open Mixing/Loading and Open-cab Application Using Label-specified PPE:

- Mixer/loader scenarios (using chemical-specific data):
 - Sugar beets at 3 & 4.95 lbs ai/A (MOEs = 7.4 and 5, respectively)

Closed Mixing/Loading and Closed-cab Application (i.e., engineering controls):

- Mixer/loader scenarios (using surrogate exposure data):
 - All scenarios (total MOE ranges from 0.12 to 0.99 based on a LOC of 10)
- Applicator scenarios (using surrogate exposure data):
 - All scenarios (total MOEs ranges from <1 to 3.9 based on a LOC of 10)

Table 8.1.2. Occupational Handler Non-Cancer Exposure and Risk Estimates for Aldicarb.									
Open Pour/Open Cab Application Using Label-Required PPE (Double layer of clothing and PF5 Respirator) Using Chemical-Specific Data.									
Crop or Target	Dermal Unit Exposure (µg/lb ai) ¹ [Level of PPE]	Inhalation Unit Exposure (µg/lb ai) ¹ [Level of PPE]	Maximum Application Rate (lb ai/A) ²	Area Treated Daily (Acres) ³	Dermal		Inhalation		Total
					Dose (mg/kg/day) ⁴	MOE (LOC = 10) ⁵	Dose (mg/kg/day) ⁶	MOE (LOC = 10) ⁷	MOE (LOC = 10) ⁸
Mixer/Loader (Load Granules – tractor drawn spreader)									
Sweet potato [e.g., nematodes]	0.22 [DL/G]	0.014 [PF5]	3	80	0.00066	20	0.000042	310	19
			1.5		0.00033	39	0.000021	620	37
Sugar beet [e.g. nematodes]			4.95	200	0.00273	4.8	0.000174	75	4.5
Sugar beet [leafminers/leafhoppers]			3		0.00165	7.9	0.000105	120	7.4
Dry bean [nematodes]; Sugar beet [aphids]; Cotton [side-dress applications]			2.1		0.00116	11	0.0000735	180	10
Peanut [nematodes /post-pegging]			1.5		0.000825	16	0.0000525	250	15
Dry bean [aphids]; Cotton [nematodes]; Peanuts [nematodes/thrips]; Soybean [mexican bean beetle/thrips]			1.05		0.000578	22	0.0000368	350	21
Dry bean [seedcorn maggot]; Cotton [aphids/thrips]; Soybean [nematodes/thrips]			0.75		0.000413	31	0.0000263	490	29
Applicator (granules – tractor-drawn spreader)									
Sweet potato [e.g., nematodes]	0.089 [DL/G]	0.0026 [PF5]	3	80	0.000268	49	0.0000078	1700	48
			1.5		0.000134	97	0.0000039	3300	94
Sugar beet [e.g. nematodes]			4.95	200	0.0011	12	0.0000321	400	12
Sugar beet [leafminers/leafhoppers]			3		0.000668	19	0.0000195	670	18
Dry bean [nematodes]; Sugar beet [aphids]; Cotton [side-dress applications]			2.1		0.000468	28	0.0000136	960	27
Peanut [nematodes /post-pegging]			1.5		0.000334	39	0.00000975	1300	38
Dry bean [aphids]; Cotton [nematodes]; Peanuts [nematodes/thrips]; Soybean			1.05		0.000234	56	0.00000683	1900	54

Table 8.1.2. Occupational Handler Non-Cancer Exposure and Risk Estimates for Aldicarb. Open Pour/Open Cab Application Using Label-Required PPE (Double layer of clothing and PF5 Respirator) Using Chemical-Specific Data.									
Crop or Target	Dermal Unit Exposure (µg/lb ai) ¹ [Level of PPE]	Inhalation Unit Exposure (µg/lb ai) ¹ [Level of PPE]	Maximum Application Rate (lb ai/A) ²	Area Treated Daily (Acres) ³	Dermal		Inhalation		Total
					Dose (mg/kg/day) ⁴	MOE (LOC = 10) ⁵	Dose (mg/kg/day) ⁶	MOE (LOC = 10) ⁷	MOE (LOC = 10) ⁸
[mexican bean beetle/thrips]									
Dry bean [seedcorn maggot]; Cotton [aphids/thrips]; Soybean [nematodes/thrips]			0.75		0.000168	77	0.00000488	2700	75

1 Based on MRID 43852501; The study inhalation unit exposure (0.07 ug/lb ai) representative of baseline protection (i.e. no respirator) was adjusted to represent use of a PF5 respirator (i.e., 80% reduction in exposure). PF5 = a NIOSH-approved respirator with a dust-mist filter with MSHA/NIOSH approval number prefix TC-21 or any N, R, P or HE filter.

2 Based on registered label (Reg. No. 87895-00001).

3 Exposure Science Advisory Council Policy #9.1.

4 Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre) × Area Treated (A/day) × DAF (100%) ÷ BW (80 kg).

5 Dermal MOE = Dermal BMDL10 (0.013 mg/kg/day) ÷ Dermal Dose (mg/kg/day).

6 Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre) × Area Treated (A/day) ÷ BW (80 kg).

7 Inhalation MOE = Inhalation BMDL10 (0.013 mg/kg/day) ÷ Inhalation Dose (mg/kg/day).

8 Total MOE = BMDL10 (0.013 mg/kg/day) ÷ [Dermal Dose + Inhalation Dose]

Table 8.1.3. Occupational Handler Non-Cancer Exposure and Risk Estimates for Aldicarb. Engineering Controls.									
Crop or Target	Dermal Unit Exposure (µg/lb ai) ¹ [Level of PPE]	Inhalation Unit Exposure (µg/lb ai) ¹ [Level of PPE]	Maximum Application Rate (lb ai/A) ²	Area Treated Daily (Acres) ³	Dermal		Inhalation		Total
					Dose (mg/kg/day) ⁴	MOE (LOC = 10) ⁵	Dose (mg/kg/day) ⁶	MOE (LOC = 10) ⁷	MOE (LOC = 10) ⁸
Loader (Load Granules – tractor drawn spreader)									
Sweet potato [e.g., nematodes]	8.6 [EC]	0.083 [EC]	3	80	0.0258	0.5	0.000249	52	0.5
			1.5		0.0129	1	0.000125	100	0.99
Sugar beet [e.g. nematodes]			4.95	200	0.106	0.12	0.00103	13	0.12
Sugar beet [leafminers/leafhoppers]			3		0.0645	0.2	0.000623	21	0.2
Dry bean [nematodes]; Sugar beet [aphids]; Cotton [side-dress applications]			2.1		0.0451	0.29	0.000436	30	0.29
Peanut [nematodes /post-pegging]			1.5		0.0323	0.4	0.000311	42	0.4
Dry bean [aphids]; Cotton [nematodes]; Peanuts [nematodes/thrips]; Soybean			1.05		0.0226	0.58	0.000218	60	0.57

**Table 8.1.3. Occupational Handler Non-Cancer Exposure and Risk Estimates for Aldicarb.
Engineering Controls.**

Crop or Target	Dermal Unit Exposure (µg/lb ai) ¹ [Level of PPE]	Inhalation Unit Exposure (µg/lb ai) ¹ [Level of PPE]	Maximum Application Rate (lb ai/A) ²	Area Treated Daily (Acres) ³	Dermal		Inhalation		Total
					Dose (mg/kg/day) ⁴	MOE (LOC = 10) ⁵	Dose (mg/kg/day) ⁶	MOE (LOC = 10) ⁷	MOE (LOC = 10) ⁸
[mexican bean beetle/thrips]									
Dry bean [seedcorn maggot]; Cotton [aphids/thrips]; Soybean [nematodes/thrips]			0.75		0.0161	0.81	0.000156	83	0.8
Applicator									
Sweet potato [e.g., nematodes]	2.0 [EC]	0.22 [EC]	3	80	0.006	2.2	0.00066	20	2
			1.5		0.003	4.3	0.00033	39	3.9
Sugar beet [e.g. nematodes]			4.95	200	0.0248	0.52	0.00273	4.8	0.47
Sugar beet [leafminers/leafhoppers]			3		0.015	0.87	0.00165	7.9	0.78
Dry bean [nematodes]; Sugar beet [aphids]; Cotton [side-dress applications]			2.1		0.0105	1.2	0.00116	11	1.1
Peanut [nematodes /post-pegging]			1.5		0.0075	1.7	0.000825	16	1.5
Dry bean [aphids]; Cotton [nematodes]; Peanuts [nematodes/thrips]; Soybean [mexican bean beetle/thrips]			1.05		0.00525	2.5	0.000578	22	2.2
Dry bean [seedcorn maggot]; Cotton [aphids/thrips]; Soybean [nematodes/thrips]			0.75		0.00375	3.5	0.000413	31	3.1

1 Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (September, 2015) as noted; Level of mitigation: Eng. Controls.

2 Based on registered label (Reg. No. 87895-00001).

3 Exposure Science Advisory Council Policy #9.1.

4 Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre) × Area Treated (A/day) × DAF (100%) ÷ BW (80 kg).

5 Dermal MOE = Dermal BMDL10 (0.013 mg/kg/day) ÷ Dermal Dose (mg/kg/day).

6 Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre) × Area Treated (A/day) ÷ BW (80 kg).

7 Inhalation MOE = Inhalation BMDL10 (0.013 mg/kg/day) ÷ Inhalation Dose (mg/kg/day).

8 Total MOE = BMDL10 (0.013 mg/kg/day) ÷ [Dermal Dose + Inhalation Dose]

Handler Risk Characterization:

The occupational handler scenarios assessed represent low dust formulations, while the surrogate data used to assess engineering controls are from studies using clay granules which are known to be more friable (i.e., more dusty) than engineered low dust formulations such as used for aldicarb. The low-dust vinyl-coated scenarios associated with the closed loading scenario have lower exposure potential than the clay-based substrate surrogate in the surrogate engineering control unit exposures.

HED notes that qualitatively the occupational exposure using engineering controls for any given handling or loading scenario is lower than the available chemical-specific handler data (occupational handlers with PPE). While the available chemical-specific study is representative of the low-dust formulation, it cannot be used to estimate exposure from the use of engineering controls (i.e., closed loading and closed cab applications). HED acknowledges that the unit exposures for the use of engineering controls with the low-dust formulation should be less than those identified in the study for use of open pour/open cab application. It is noted that based on the surrogate unit exposure guide, closed loading/closed cab systems often provide up to 90% reduction in exposure.

9.2 Occupational Post-application Exposure/Risk Estimates

HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Post-application exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for post-application exposure.

9.2.1 Occupational Post-application Inhalation Exposure/Risk Estimates

There are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037>). The agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis ([HYPERLINK "http://www.regulations.gov/" \l "'!docketDetail;D=EPA-HQ-OPP-2014-0219"]). During Registration Review, the Agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for aldicarb.

In addition, the Agency is continuing to evaluate the available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. Given these two efforts, the Agency will continue to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the agency's risk assessments.

9.2.2 Occupational Post-application Dermal Exposure/Risk Estimates

A quantitative post-application assessment has not been conducted for aldicarb because aldicarb is soil incorporated and there is limited potential for worker dermal exposure to soil incorporated pesticides.

In accordance with 40 CFR 158, dislodgeable foliar residue (DFR) data are required for all occupational (e.g., crop, nursery, greenhouse use sites) or residential (e.g., ornamental and vegetable gardens, pick your own farms, retail tree farms) uses that could result in post-application exposure to foliage. In the case of aldicarb, there are no currently labeled uses that would result in foliar residue; therefore, no DFR data are required at this time. In the case that the registered use pattern changes, HED would reevaluate the need for a DFR study, depending on the proposed label change.

The REI specified on the existing labels [48 hours] is based on the acute toxicity of aldicarb. Aldicarb is classified as Toxicity Category I via the dermal, oral, and inhalation routes of exposure. Due to severe effects (death) following corneal and dermal dosing, dermal and eye irritation studies were waived in the acute toxicity database. Because of the limited worker exposure profile (soil-incorporation), the REI on the labels is adequate to protect for worker exposure. Therefore, the [156 subpart K] Worker Protection Statement interim REI of 48 hours is adequate to protect agricultural workers from post-application exposures to aldicarb.

Appendix A. Summary of Occupational and Residential Non-cancer Algorithms

Occupational Non-cancer Handler Algorithms

Potential daily exposures for occupational handlers are calculated using the following formulas:

$$E = UE * AR * A * 0.001 \text{ mg/ug}$$

where:

E = exposure (mg ai/day),
UE = unit exposure (µg ai/lb ai),
AR = maximum application rate according to proposed label (lb ai A or lb ai/gal), and
A = area treated or amount handled (e.g., A/day, gal/day).

The daily doses are calculated using the following formula:

$$ADD = \frac{E * AF}{BW}$$

where:

ADD = average daily dose absorbed in a given scenario (mg ai/kg/day),
E = exposure (mg ai/day),
AF = absorption factor (dermal and/or inhalation), and
BW = body weight (kg).

Margin of Exposure: Non-cancer risk estimates for each application handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the toxicological endpoint to the daily dose of concern. The daily dermal and inhalation dose received by occupational handlers are compared to the appropriate POD (i.e., NOAEL) to assess the risk to occupational handlers for each exposure route. All MOE values are calculated using the following formula:

$$MOE = \frac{POD}{ADD}$$

where:

MOE = margin of exposure: value used by HED to represent risk estimates (unitless),
POD = point of departure (mg/kg/day), and
ADD = average daily dose absorbed in a given scenario (mg ai/kg/day).

Occupational Non-cancer Post-application Algorithms

Potential daily exposures for occupational post-application workers are calculated using the following formulas:

$$DFR_t = AR * F * (1-D)^t * \left(4.54E8 \frac{ug}{lb}\right) * \left(2.47E-8 \frac{A}{cm^2}\right)$$

where:

DFR_t = dislodgeable foliage residue on day "t" (µg/cm²),
 AR = application rate (lb ai/acre),
 F = fraction of ai retained on foliage or 25% (unitless),
 D = fraction of residue that dissipates daily or 10% (unitless), and
 t = number of days after application day (days).

$$E = TC * DFR_t * ET * 0.001 \frac{mg}{ug}$$

where:

E = exposure (mg ai/day),
 TC = transfer coefficient (cm²/hr),
 DFR_t = dislodgeable foliar residue on day "t" (µg/cm²), and
 ET = exposure time (hours/day).

The daily doses are calculated using the following formula:

$$ADD = \frac{E * AF}{BW}$$

where:

ADD = average daily dose absorbed in a given scenario (mg ai/kg/day),
 E = exposure (mg ai/day),
 AF = absorption factor (dermal and/or inhalation), and
 BW = body weight (kg).

Margin of Exposure: Non-cancer risk estimates for each scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the toxicological endpoint to the daily dose of concern. The daily dermal dose received by occupational post-application workers is compared to the appropriate POD (i.e., NOAEL) to assess the risk to occupational post-application workers. All MOE values are calculated using the following formula:

$$MOE = \frac{POD}{ADD}$$

where:

MOE = margin of exposure: value used by HED to represent risk estimates (unitless),
POD = point of departure (mg/kg/day), and
ADD = average daily dose absorbed in a given scenario (mg ai/kg/day).

Appendix B. Summary of Available Occupational Handler Exposure Data

One chemical-specific study was submitted in support of the reregistration of aldicarb, and was judged to be appropriate for use in occupational exposure/risk assessments. These data have not been integrated with PHED for this assessment because the granules used are vinyl coated formulation (i.e., a “low dust formulation”) which is likely to lead to differences in exposure. The study can be identified by the following information:

EPA MRID 43852501: Rosenheck, L., Schuster, L. (1995) Worker Loader and Applicator Exposure to Temik 15G. Study number 94388, Unpublished study prepared by ABC Laboratories, Pan-Ag Division; Rhone-Poulenc Ag Company.

This study quantified exposure to aldicarb for workers loading and applying Temik 15G (EPA Reg. No. 264-330) at the maximum rate of 6 lb ai/acre in pecan groves using shank injection. Dermal and inhalation exposure levels to aldicarb and its two principal by-products, aldicarb sulfoxide and aldicarb sulfone, were measured. Five replicates of the loading and application of Temik 15G were monitored at each of the three locations for a total of 15 loading and 15 application replicates (mixer/loaders were monitored separately from the applicators). The study was conducted in three locations; Raymond, Mississippi; Brownwood, Texas; and Albany, Georgia.

The use of a modified Tye seeder in the three different locations was consistent with commercial agricultural practice (i.e., recommended equipment for aldicarb applications). The test subjects also wore protective clothing that met U.S. EPA Worker Protection Standards, consisting of nitrile rubber gloves, rubber boots, goggles, hard hat, a dust filtering respirator and a chemical resistant apron (loader only) over short-sleeved shirt, short pants and coveralls. The duration of each loading replicate was approximately 4 hours, and during this time the modified seeder was loaded and emptied twice (once at the start and again after about 2 hours). The application replicates were monitored using open cab tractors over a period of approximately 4 hours. The loaders handled a range of 900 lb to 1485 lb of Temik 15G (135 lb to 223 lb ai) per replicate. The average application rate was approximately 40 lb product per acre (6 lb ai/A, the maximum rate). Aldicarb was packaged in 45 pound bags and open cab tractors were used.

Dermal exposures were monitored using whole-body dosimetry (long underwear, later sectioned into arms, chest, back, and lower body), handwashes and facial and neck swipes. The long underwear (100% cotton) was worn under short pants and a short sleeved shirt. Hand exposure was monitored by having each test subject remove gloves and wash both hands twice in detergent solution (0.01% v/v Aerosol OT 75). Face and neck exposures were monitored by wiping the face and neck with 10 percent cotton gauze pads wet with the detergent solution. Inhalation exposures were monitored using a XAD2 resin tube, polyurethane foam, and glass fiber filter to collect both vapor and particulate matter. The tubes were attached to a personal air pump with a flow rate of approximately 1.5 liters/minute. The limits of quantification (LOQs) for each matrix are presented in Table 1.

Table 3: Limits of Quantification and Detection in Study						
Area	LOQ (µg/ml)	<LOQ-Replicates		LOD (µg/ml)	Non-detects-Replicates	
		Loader	Applicator		Loader	Applicator
Dermal:						
Arm, chest, back	1.00	21:45	25:45	0.40	6:45	6:45
Lower Body	2.00	0:15	3:15	0.67	0:15	2:15
Handwash	1.00	1:15	2:15	0.30	0:15	2:15
Facial Wipe	0.10	4:15	2:15	0.01	0:15	0:15
Inhalation:						
OVS Tube	0.05	1:15	6:15	0.020	0:15	1:15
<p>a LOD = Minimum Standard Concentration Tested (0.01µg/ml) * Dilution Factor.</p> <p>Arm, chest, back Dilution Factor = 40</p> <p>Lower Body Dilution Factor = 67</p> <p>Handwash Dilution Factor = 30</p> <p>Facial Wipe Dilution Factor = 1</p> <p>OVS Tube Dilution Factor = 1</p> <p>Note: For Loaders: Aldicarb 38 of 90 samples were <LOQ, 11 of 90 samples were <LOD, Aldicarb sulfone 79 of 90 samples were < LOQ, 47 of 90 samples were <LOD and aldicarb sulfoxide 56 of 90 samples were < LOQ, 20 of 90 samples were <LOD.</p> <p>For Applicators: Aldicarb 56 of 90 samples were <LOQ, 15 of 90 samples were <LOD, Aldicarb sulfone 83 of 90 samples were < LOQ, 55 of 90 samples were <LOD and aldicarb sulfoxide 79 of 90 samples were < LOQ, 27 of 90 samples were <LOD.</p>						

For detected peaks whose values fell below the LOQ but above the limit of detection (LOD), results were reported as 50 percent of the LOQ. This is within current Agency guidelines. However, when the results fell below the LOD (i.e. "no peak detected"), the study reported the result as only 10 percent of the LOQ. The study did not mention the LOD value used for this interpretation.

In place of the 10 percent LOQ value given non-detects, 50 percent LOD was used in the exposure calculations. The LOD for each matrix was calculated based on the lowest quantifiable level in the calibration curve as presented in the analytical methods section of the study.

The study was conducted in accordance with most of 875 Guidelines Group A, Applicator Monitoring Exposure Test Guidelines. Field recovery for aldicarb, aldicarb sulfoxide, and aldicarb sulfone are presented in Table 2.

Table 2: Field Fortification Recoveries.				
Matrix	Field Percent Recovery (CV %)*			n
	Aldicarb	Aldicarb Sulfoxide	Aldicarb Sulfone	
Inhalation Tube	77 (4)	NA	NA	8
Handwash	78 (13)	75 (5)	90 (11)	8
Facial Swab	84 (7)	92 (5)	92 (4)	8
Body Dosimeter	83 (7)	81 (5)	91 (3)	8

* CV = standard deviation ÷ mean

Laboratory recovery for aldicarb, aldicarb sulfoxide and aldicarb sulfone is presented in Table 3. Storage stability data were acceptable. Control samples had residues less than the LOQ and the recoveries were within the EPA acceptable range of 70-120%.

Table 3: Laboratory Recoveries.			
Matrix	Laboratory Percent Recovery (CV %, n)		
	Aldicarb	Aldicarb Sulfoxide	Aldicarb Sulfone
Inhalation Tube	81 (16, n=24)	84 (12, n=24)	83 (10, n=24)
Handwash	93 (7.6, n=17)	83 (9.7, n=17)	98 (7.7, n=17)
Facial Swab	90 (13, n=13)	90 (9.7, n=13)	92 (11, n=13)
Body Dosimeter	83 (16, n= 21)	89 (12, n=21)	96 (10, n=21)

The values used in risk assessment were adjusted for field recovery (results below 90 percent increased to 100 percent) and normalized to mg (μg for inhalation) of aldicarb exposure per lb of aldicarb handled (incorporating the 50 percent LOD value for non-detects and 50 percent LOQ for values below the LOQ). The values calculated are presented in Table 4.

Table 4: Results from Aldicarb Pecan Loader and Applicator Study.						
Task	Dermal (mg ai exposure/ lb ai handled)			Inhalation (μg ai exposure/ lb ai handled)		
	Arithmetic Mean*	Geometric Mean	Median	Arithmetic Mean*	Geometric Mean	Median
Loader	0.00022	0.00019	0.00017	0.070	0.025	0.022
Applicator	0.000089	0.000081	0.000078	0.013	0.0044	0.0044

* Used as the unit exposure for occupational risk estimation